

# Cannabinoid profile and regulatory compliance of non-scheduled cannabinoid-containing products in South Africa

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## The Cannabis Plant

The cannabis plant has a complex biological profile<sup>1,2</sup>

- Numerous medicinal benefits and properties

Over 60 cannabinoids

- $\Delta^9$ -Tetrahydrocannabinol (THC) and cannabidiol (CBD) are the most well-known, widely-researched cannabinoids<sup>3,4</sup>

Variety of cannabis products available<sup>5</sup>

- Many are unscheduled and unregulated
- Liquids, tablets, sprays, balms or cigarettes

Medicinal /recreational cannabis legislation varies globally

- Status is considered either legal, illegal or decriminalised

South African cannabis legislation

- Personal consumption of for private use is legal<sup>6</sup>
- >20 mg CBD daily and >600 mg CBD per sales pack considered schedule 0

## Methods

Six CBD oils were purchased in a summer and winter batch to assess cannabinoid content and batch-to-batch conformity

- These are referred to as referred to as CBD Oil 'A', 'B', 'C', 'D', 'E' and 'F'

Targeted LC-MS/MS method and analysis

- Analytes of interest: THC, CBD, cannabiol (CBN) and tetrahydrocannabinolic Acid-A (THCA)

- C18 Phenomenex Gemini column (2 x 100 mm)

- Isocratic gradient programme; 10 mM ammonium formate in water: acetonitrile (0.1% formic acid) 32.5:67.5 at a flow rate of 0.4 mL/min for 13 minutes

The immediate and outer container labels of all CBD oils were scrutinized to determine compliance to labelling regulations

Optimised method was validated according to International Conference on Harmonisation (ICH) guidelines

Limit of detection (LOD) was determined by the calibration curve for each analyte

## Results

All CBD oils failed to meet label claims (Figure 1)  
Advertised CBD content was mislabelled in most CBD oils

### Underlabeling of CBD oils

- Three contained between one quarter and one half above the advertised CBD content
- Two contained double the advertised CBD content
- Two contained triple the advertised CBD content

### Overlabeling of CBD oils

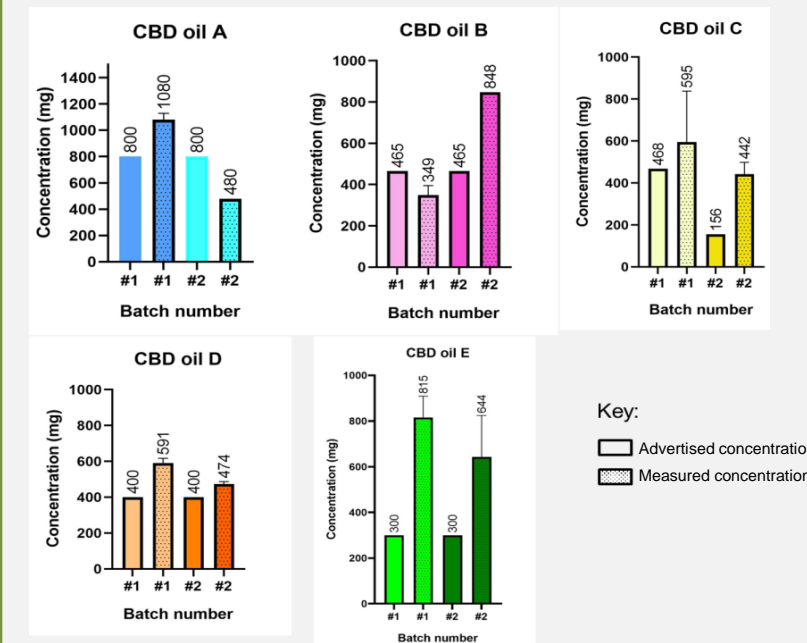
- Two contained between a quarter and a half less than advertised CBD content

Concentrations of THC, CBN and THCA were not detected in significant amounts in 5 out of 6 CBD oils

- (<0 mg/mL, with detection limits of 293.2 ng/mL (THC), 30.9 ng/mL (THCA) and 47.2 ng/mL (CBN))

High concentrations of both THC and CBN were detected in one CBD oil (Table 1)

- 47.97 mg THC and 15.4 mg CBN in batch 1
- 131.5 mg THC and 26.3 mg CBN in batch 2



**Figure 1:** The difference between advertised and measured CBD concentration in the first and second batches of purchased CBD oils (CBD oil F is excluded as the advertised CBD concentration was not listed on the outer container)

**Table 1:** Average measured cannabinoid content in CBD oil F determined from duplicate runs

Batch number	Measured CBD concentration per bottle (mg)	Measured THC concentration per bottle (mg)	Measured CBN concentration per bottle (mg)
1	0	47.97	15.4
2	5	131.5	26.3

## Discussion

Disparity between advertised and measured CBD content  
Possibly due to

- Differences in the form of cannabinoid extraction and detection methods employed
- The type of cannabis strain used

Absence of batch-to-batch conformity noted for all samples across both batches

- Differences in cannabinoid content were observed
- Possible consequence of seasonal variation in cannabis plants used for production

An inspection of the immediate and outer container labels show

- 5 out of 6 CBD oils complied with most labelling requirements stipulated by The Medicines and Related Substances Act (Act 101 of 1965)
- 1 CBD oil contained no labels besides proprietary name

Additional labels are recommended to be added, including

- Warnings (pregnancy, driving, adverse reactions)
- Additional safety information

## Conclusion

South Africa still has many hurdles to overcome in terms of effective cannabis regulation, and measures need to be implemented to ensure unscheduled cannabis products used for medicinal purposes adhere to local regulations. The importance of cannabis education cannot be underestimated; both cannabis users and health care professionals must be well-informed on clinical and legislative aspects to encourage a sustainable and bright future for the South African cannabis industry.

### Acknowledgments

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